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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/420,695	10/19/99	THANAVALA	Y RPP:156A-US

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EXAMINER	
FLOOD, M	
ART UNIT	**PAPER NUMBER**
1651	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/420,695	Applicant(s) Thanavala et al.
	Examiner Michele Flood	Group Art Unit 1651

☒ Responsive to communication(s) filed on *Oct 19, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *7*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is made vague and indefinite by the phrase "providing an immune response" because the meaning of the phrase is unclear. Ambiguity exists in the identification of the process. Therefore, it is uncertain as to what subject matter Applicant regard as the claimed invention. In what way is an immune response provided to an animal? Is the claimed invention directed to a method of primary immunization? Or, is the claimed invention directed to a method of secondary immunization? Does applicant intend a protective immune response in the meaning of "providing an immune response"? The lack of clarity makes the claim very indefinite.

All of the claims are made vague and indefinite by the phrase "wherein the animal is made immunoreceptive to HBsAg" because it is unclear as to the meaning of the phrase. "Immunoreceptive" is not a term recognized in the art of immunology. In what way is an animal made immunoreceptive to an antigen? It is uncertain whether the animal was previously "made immunoreceptive" by other means of receiving immunity or whether the animal is "made

immunoreceptive" by the method claimed in the invention of the applicant. Does applicant intend a protective immune response in the meaning of " wherein the animal is made immunoreceptive to HBsAg"? The lack of clarity makes the claim indefinite.

Regarding Claim 1, it appears that a step in the claimed process is missing because it is not apparent in what way the animal is made immunoreceptive to the hepatitis B surface antigen. Was the animal made immunoreceptive to the HBSAG by exposure to the antigen via a contaminated biological material, such as blood or mother's milk? Or, was the animal made immunoreceptive to the HBsAg by artificial immunization, such as a vaccine. It would appear that any animal with a health immune response is immunoreceptive to an antigen, if the animal is exposed to the antigen; and, thus shows an immune response upon exposure to the antigen. There is no apparent difference, even in light of Applicant's definition of the terms, in the terms "providing an immune response" or "made immunoreceptive", immunoreceptive could mean the ability of an individual to demonstrate an immune response upon the exposure of the individual to the antigen.

Regarding Claim 4, it would appear that there is no difference in the phrase "providing an immune response in an animal or human made immunoreceptive" and the phrase "an animal or human having a positive response to primary immunization" as both phrases encompass the same scope. Applicant's recitation of the aforementioned phrases make the claims vague and indefinite. Ambiguity exists in the identification of the process. Therefore, it is uncertain as to what subject matter Applicant regard as the claimed invention. The lack of clarity makes the Claims indefinite.

There is an apparent misplaced period at the end of line 2 in Claim 3. Applicant may overcome the rejection by removing the misplaced period.

Claim 2 recites the limitation "the substance" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "the substance material" in lines 3 and 4. There is insufficient antecedent basis for this limitation in the claim.

Regarding Claims 14-15, the term "*solanaceae*" should be replaced with *Solanaceae*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claim 19 is rejected under 35 U.S.C. as being anticipated by Arntzen et al. (B).

Applicant claims a physiologically acceptable material containing hepatitis B surface antigen.

Arntzen teaches a transgenic plant material capable of being ingested for its nutritional value. The transgenic plant material is a tomato or potato which contains the hepatitis B surface antigen. The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arntzen (B) or Koprowski (A) and in view of Stites et al. (U).

Applicant claims a method for providing an immune response to hepatitis B surface antigen (HBSAG), in an animal made immunoreceptive to HBSAG, by feeding the immunoreceptive plant material containing hepatitis B surface antigen. Applicant further claims a method wherein the animal is made immunoreceptive to HBsAg by immunization against hepatitis B prior to feeding the animal the substance. Applicant further claims the plant material is tuber material from a potato.

Arntzen teaches an anti-viral vaccine produced in physiologically acceptable plants, particularly the potato and the tomato, and then administered through standard vaccine procedure or by feeding the plants to an animal or a human. Arntzen specifically teaches methods of making a transgenic plant expressing an immunogen derived from hepatitis B surface antigen, wherein the immunogen is capable of eliciting an immune response in an animal or a human by consumption of the said plant material. Arntzen also teaches methods of making a vaccine by recovering the immunogen expressed in the plant cell for use as a vaccine. Koprowski, also, teaches methods of making a transgenic plant containing a viral antigen which is fed to an animal or a human to elicit an immune response. Koprowski teaches a process for the genetic alteration of a microorganism such that it synthesizes an immunologic compound and produces an immunologic effect in an animal or a human. A plant may be infected with the genetically altered microorganism and used as an oral delivery system. The vaccine or therapeutic compound, if administered by the oral route, is done by feeding the animal or human a physiologically acceptable plant material containing the immunogen. See Column 5, lines 54-61. The vaccine can further comprise an adjuvant to facilitate or improve activity. See Column 6, lines 33-36. Koprowski teaches, in Column 8, lines 1-31, plant infecting microorganisms and plant hosts that can be used against the invention, including tuber material from the potato plant. Neither Arntzen nor Koprowski teach a method for providing an immune response in an animal made immunoreceptive to hepatitis B surface antigen by immunization prior to feeding the hepatitis B surface antigen-immunoreceptive animal a physiologically acceptable plant material containing hepatitis B surface antigen.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an immune response to hepatitis B antigen in a hepatitis B surface antigen-immunoreceptive animal by immunizing the hepatitis B surface antigen-immunoreceptive animal prior to feeding the animal a physiologically acceptable plant material containing hepatitis B surface antigen because Stites teaches that reimmunization in a previously immune individual provides a rapid secondary increase in immunity. See page 724, Column 2, lines 1-42. Both Arntzen and Koprowski expressly teach methods of providing an immune response in an animal by either feeding a genetically altered plant containing HBSAG or preparing a vaccine from a genetically altered plant containing an HBsAg that can be delivered through standard immunization procedures and one would have been motivated to modify the teachings of either Arntzen or Koprowski by adding an additional step wherein an animal made immunoreceptive to HBsAg was immunized against hepatitis B prior to feeding the animal plant material genetically altered to express the antigen because both of the references of Arntzen and Koprowski teach that the oral vaccine delivery systems provide positive humoral and mucosal immune responses, whether by oral ingestion or parenteral administration. Thus, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success that the method of the claimed invention would provide a furthering immune response in an animal previously made immunoreceptive to HBsAg by ingesting the plant materials taught by either Arntzen or Koprowski.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 4-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arntzen (B) in view of Stites et al. (U), and further in view of and Koprowski (A).

Applicant claims a method for boosting an immune response to hepatitis B surface antigen in a human previously having a positive response to primary immunization against hepatitis B, and a therapeutic regimen thereof.

The teachings of Arntzen and Koprowski are set forth above. Neither Arntzen nor Koprowski teach a method for boosting an immune response to hepatitis B antigen in a human.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to induce a booster response in a human having a positive response to primary immunization against hepatitis B surface antigen, wherein the method comprises the human ingesting a genetically altered potato or tomato containing hepatitis B surface antigen because Stites teaches on page 724, Column 2, lines 1-42, the principles of "booster" reimmunization in a previously immune individual. One would have been motivated to optimize the methods of oral immunization as taught by either Arntzen and Koprowski by inducing a secondary immune response in a human wherein the human ingests a genetically altered potato or tomato containing hepatitis B surface antigen comprising a therapeutic regimen of ingesting the said plant material in a plurality of different times because Stites teaches, on page 724, lines 28-32, that the timing of primary immunization, the interval doses, and the timing of booster

administrations are based on both theoretic considerations and vaccine administrations. One of ordinary skill in the art at the time the invention was made would have been motivated to use a genetically altered plant from the *Solanaceae* family because Koprowski expressly teaches, in Column 8, lines 24-31, solanaceous plants which are physiologically acceptable plant material that can be genetically altered and used in the delivery of oral vaccines for therapeutic purposes. One of ordinary skill in the art at the time the invention was made would have been further motivated to use a substance comprising a physiologically acceptable plant material containing hepatitis B surface antigen because Arntzen teaches, in Column 6, lines 21-36, that the oral vaccines produced in the taught invention are inexpensive sources of antigen which are delivered by the ingestion of edible plant material parts, including tuber material. Arntzen clearly teaches methods of providing an oral delivery system for a vaccine, wherein a potato or tomato plant contains a hepatitis B surface antigen. Finally, one would have had a reasonable expectation of success to use the methods and materials taught by Arntzen and/or Koprowski because the determination of an effective treatment method for boosting the immune response in a human to hepatitis B surface antigen previously having a positive response to primary immunization against hepatitis B which comprised the ingestion of genetically altered plant material would have been a matter of routine optimization to one of ordinary skill in the art at the time the invention was made.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Double Patenting

Claims 3-14 and 16 of this application conflict with claims 2, 4, 6, 8-15, 17 and 19 of Application No. 09/464,414. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 1-2 of this application conflict with claims 2 and 14 of Application No. 09/464,416. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 1-20 of this application conflict with claims 1-20 of Application No. 09/418,177. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one

application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-20 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-20 of copending Application No. 09/418,177. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 3-14 and 16 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2, 4, 6, 8-15, 17 and 19 of copending Application No. 09/464,414. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-2 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2 and 14 of copending Application No. 09/464,416. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No.5,914,123. Although the conflicting claims are not identical, they are not patentably distinct from each other because the products and method of use of the products of U.S. Patent No. 5,914,123 appear to be identical.

Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 09/464,416. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed inventions are directed to the same subject matter and the scopes of the claimed inventions are obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 09/464,414. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed inventions are directed to the same subject matter and the scopes of the claimed inventions are obvious variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-4932. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

LEON B. LANKFORD, JR
PRIMARY EXAMINER

mcf

April 4, 2000